

Environmental Protection Agency

§ 725.94

§ 725.92 Data from health and safety studies of microorganisms.

(a) *Information other than specific microorganism identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study of a microorganism, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a microorganism.

(2) Information which is not in any way related to the effects of a microorganism on health or the environment, such as, the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with § 725.80.

(b) *Microorganism identity*—(1) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use.* A claim of confidentiality for the period prior to commencement of manufacture or import for general commercial use for the specific identity of a microorganism for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under § 725.85(a). The submitter must substantiate each claim in accordance with the requirements of § 725.94(a).

(2) *Claims applicable to the period after commencement of manufacture or import for general commercial use.* To maintain the confidential status of the specific identity of a microorganism for which a health and safety study was submitted after commencement of manufacture or import for general commercial use, the claim must be reasserted and substantiated in conjunction with a claim under § 725.85(b). The submitter must substantiate each claim in accordance with the requirements of § 725.94(b).

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for microorganism identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a microorganism.

(2) The microorganism identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a microorganism identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the microorganism by the generic name selected under § 725.85.

§ 725.94 Substantiation requirements.

(a) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use*—(1) *MCAN, TME, Tier I certification, and Tier II exemption request requirements.* Any person who submits a MCAN, TME, Tier I certification, or Tier II exemption request should strictly limit confidentiality claims to that information which is confidential and proprietary to the business.

(i) If any information in the submission is claimed as confidential business information, the submitter must substantiate each claim by submitting written answers to the questions in paragraphs (c), (d), and (e) of this section at the time the person submits the information.

(ii) If the submitter does not provide written substantiation as required in paragraph (a)(1)(i) of this section, the submission will be considered incomplete and the review period will not begin in accordance with § 725.33.

(2) *TERA requirements.* Any person who submits a TERA, should strictly limit confidentiality claims to that information which is confidential and proprietary to the business. If any information in such a submission is claimed as confidential business information, the submitter must have available for each of those claims, and agree to furnish to EPA upon request, written answers to the questions in paragraphs (d) and (e) of this section.

(b) *Claims applicable to the period after commencement of manufacture or import for general commercial use.* (1) If a submitter claimed portions of the microorganism identity confidential in the MCAN and wants the identity to be listed on the confidential Inventory,